DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 6, 2014

Xavant Technology (Pty) Limited
Mr. Roche van Rensburg
Chairman
Ravello 1st Floor, Delmondo Office Park
169 Garsfontein Road
Ashlea Gardens
Pretoria, Gauteng 0081
SOUTH AFRICA

Re: K140853
Trade/Device Name: Stimpod ST2-3010 Nerve Stimulator
Regulation Number: 21 CFR 868.2775
Regulation Name: Electrical Peripheral Nerve Stimulator
Regulatory Class: II
Product Code: BXN
Dated: October 1, 2014
Received: October 10, 2014

Dear Mr. Rothman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 2

INDICATIONS FOR USE

510(k) Number (if known): K140853

Device Name: **STIMPOD ST2-3010 nerve stimulator**

Indications for Use:

The STIMPOD ST2-3010 is a nerve stimulation device designed to be used for the purpose of nerve locating using invasive electrodes or needles (not supplied)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) **AND/OR** **Over-The-Counter Use** _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

ATTACHMENT 4

510(k) SUMMARY

[As required by 21CFR807.92]

4.1 Date Prepared [21CFR807.92(a)(1)]

July 28, 2014

4.2 Submitter's Information [21CFR807.92(a)(1)]

Company Name:	XAVANT Technology (Pty) LTD
Street Address:	Ravello, 1st Floor. Delmondo Office Park 169 Garstfontein Road Ashlea Gardens
City:	Pretoria
State/Province:	Gauteng
Country:	South Africa
Telephone:	+27(0) 12 755 9491
Facsimile:	+27(0) 12 346 7271
Contact Person:	Brian Rothman
Contact Title:	Quality Assurance and Regulatory Compliance Officer
Contact Email:	brian@xavant.com

4.3 Trade Name, Common Name, Classification [21CFR807.92(a)(2)]

Trade Name:	STIMPOD ST2-3010 nerve stimulator
Common Name:	Battery Powered Peripheral Nerve Stimulator
Classification Name:	Anesthesiology per 21 CFR § 868.2775
Device Class:	Class II
Product Code:	BXN

4.4 Identification of Predicate Device(s) [21CFR807.92(a)(3)]

PREDICATE DEVICES
Xavant Technology, STIMPOD NMS450 (K102084)

There are no significant differences between the STIMPOD ST2-3010 Nerve Stimulator and the predicate devices which would adversely affect the use of the product. It is substantially equivalent to the device in design, function, materials, operational principles and intended use.

The STIMPOD NMS450 is a battery powered peripheral nerve stimulator that can be used for

- general anesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes (not supplied)
- nerve mapping using the non-invasive Nerve Mapping Probe (supplied)
- nerve locating using invasive electrodes/needles (not supplied)

The stimulus is generated by a constant current source. The waveform is a square wave with various pulse width options.

The units will continuously check for a closed circuit. Once a closed circuit is detected, the unit will deliver a stimulus until an open circuit is detected.

Once operational the unit will flash an LED when the circuit with the patient is a closed circuit and the stimulation was successfully delivered. In the case that the circuit with the patient is an open circuit, a stimulus will not be delivered.

The anode comprises of an ECG electrode (not supplied). The cathode comprises a permanently attached nerve mapping probe (supplied), and/or a separate nerve locating needle (not supplied), and/or an ECG electrode (not supplied), depending on the mode of the unit

This product is a nerve stimulation device designed to be used by an anaesthetist during

1. General anaesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes (not supplied)
2. Regional anaesthesia for the purpose of
   a) nerve mapping using the non-invasive Nerve Mapping Probe (supplied) and
   b) nerve locating using invasive electrodes/needles (not supplied)

4.5 Description of the Device [21CFR807.92(a)(4)]

The STIMPOD ST2-3010 device is a battery powered peripheral nerve stimulator that can be used for

- the purpose of nerve locating using invasive electrodes or needles (not supplied)

The STIMPOD ST2-3010 is a precision nerve locating tool used for localizing specific neural pathways. Localization of nerves by electrical stimulation involves connecting the nerve stimulator to a conducting needle.

The stimulus is generated by a constant current source. The waveform is a monophasic square wave with 3 options for pulse width. These are: 0.1, 0.2 and 0.3 milliseconds.

The unit dimensions are 145mm x 90mm x 30mm with a weight of 130 g

4.6 Intended Use [21CFR807.92(a)(5)]

This product is a nerve stimulation device designed to be used for the purpose of nerve locating using invasive electrodes or needles (not supplied).

The difference in intended use is not critical to its use and does not affect the safety and efficacy of the subject device. Both subject and predicate device are nerve stimulators. Where as the predicate device has three (3) indications for use, the subject device has only one. This is to be used for the purpose of nerve locating using invasive electrodes or needles (not supplied). The predicate device has this use listed and already has clearance.
The intended use of the subject device is limited to within the currently cleared indications of the predicate device.

4.7 Technological Characteristics [21CFR807.92(a)(6)]

Operating Modes:

Current Range:	0.00 – 10.00mA ±5% adjustable in 0.1mA increments.
Pulse Width Options:	100µs, 200µs, 300µs
Stimulus:	Monophasic square wave
Stimulating Frequency:	20Hz, 50Hz and 100Hz

Waveform:

Constant Current Monophasic Square wave

Technical Specifications

Device Classification:	Class IIa, Type BF
Power Supply:	4x AAA alkaline batteries
Power Consumption:	18mA
Maximum Stimulation Voltage:	70V
Weight:	130g
Dimensions:	145mm x 90mm x 30mm
Load Impedance:	0 kOhm – 7 kOhm
Operating Temperature:	10 – 40 Degrees Celsius (°C)
Storage and Transport Temperature:	0 – 50 Degrees Celsius (°C)
Operating Humidity:	90% Relative Humidity

Summary of technical characteristics between predicate device (STIMPOD NMS450) and new device (STIMPOD ST2-3010)

Device Name:	**STIMPOD ST2-3010**	**STIMPOD NMS450**	**Affects Indications for Use / Technology**	**Comments**
Product Components:	1. Nerve Stimulator 2. Stimulation Cable 3. IFU	1. Nerve Stimulator 2. Nerve Locating Cable 3. Nerve Mapping/Locating Cable 4. NMBA Monitoring Cable 5. IFU	NO **(e)**	Both contain a nerve stimulator and a cable. The NMS450 has additional cables for additional functions
Indications for Use:	This product is a nerve stimulation device designed to be used for the purpose of <u>nerve locating using invasive electrodes or needles (not supplied)</u>	This product is a nerve stimulation device designed to be used by an anesthetist during 1. general anesthesia, for the purpose of establishing the efficacy of a Neuromuscular Blocking Agent using non-invasive surface electrodes	NO - In this case, the indications for use are limited to within the cleared indications for use of the predicate device **(a), (c)**	Essentially, both devices are for nerve localization using invasive electrodes/needles (not supplied)

Device Name:	STIMPOD ST2-3010	STIMPOD NMS450	Affects Indications for Use / Technology	Comments
		(not supplied 2. regional anesthesia for the purpose of a. nerve mapping using the non-invasive Nerve Mapping Probe (supplied) and b. nerve locating using invasive electrodes/needles (not supplied)		
Current Ranges	0 -10mA	**Nerve Locating: 0-5mA** **Nerve mapping: 0-20mA** NMBA Mode: 0-80mA	NO **(d)**	The current range is covered
Energy Type (1)	4 X AAA alkaline batteries, 6V	4 X AAA alkaline batteries, 6V	NO **(e)**	Both units are battery powered
Activation	ON/OFF Power button	ON/OFF Power button	NO **(e)**	
Labeling:	According to **ISO 15223**	According to **ISO 15223**	NO **(d)**	
Anatomical site of use	Location of peripheral nerves	Location of peripheral nerves	NO **(a) , (b), (c)**	
Testing	**SAFETY TESTING** Passed **(IEC 60601-1) 3rd edition**	**SAFETY TESTING** Passed **(IEC 60601-1) 3rd edition**	**NO (b) , (h)**	
	RADIATED RADIO FREQUENCY ELECTROMAGNETIC FIELD 80 MHz TO 2500 MHz IEC61000-4-3 Passed	**RADIATED RADIO FREQUENCY ELECTROMAGNETIC FIELD 80 MHz TO 2500 MHz** IEC61000-4-3 Passed	**NO (b) , (h)**	
	ELECTROMAGNETIC COMPATIBILITY Passed (IEC 60601-1-2)	**ELECTROMAGNETIC COMPATIBILITY** Passed (IEC 60601-1-2)	**NO (b) , (h)**	
	Medical electrical equipment. Particular requirements for the	**Medical electrical equipment. Particular requirements for the**	**NO(b) , (h)**	

Device Name:	STIMPOD ST2-3010	STIMPOD NMS450	Affects Indications for Use / Technology	Comments
	safety of nerve and muscle stimulators **PASSED** **(IEC 60601-2-10)**	**safety of nerve and muscle stimulators** **PASSED** **(IEC 60601-2-10)**		
Weight (5)	130g	130g	NO **(e)**	Same weight
Size (unit) (5)	145mm x 90mm x 30mm	145mm x 90mm x 30mm	NO **(e)**	Identical enclosures
Enclosure (4)	Manufactured from ABS	Manufactured from ABS	NO **(i)**	Identical enclosures
Dial (4)	Tactile membrane with capacitive sensing wheel. Manufactured from polycarbonate	Tactile membrane with capacitive sensing wheel. Manufactured from polycarbonate	NO **(e)**	Same keypads, different coloring and function
LCD (4)	Not covered	Not covered	NO **(e)**	
Cable (4)	KE-PVC moulding Connector – Gold plated	KE-PVC moulding Connector – Gold plated	NO **(e), (l)**	Similar cable construction,
Packaging (7)	Non-sterile Multiple Use Packaging in a polypropylene carry case	Non-Sterile Multiple Use Packaging in a polypropylene carry case	NO **(e), (f)**	Packaged in the same way
Software (6)	Language: C Architecture - **User Inputs** ○ Keypad ○ Dial - **External Inputs** ○ Open circuit detection Low voltage ○ No Open circuit detection High voltage ○ Battery Voltage ○ Cable ID x 1 ○ No accelerometer - **Outputs** ○ Display Menu ○ Display Main Screen ○ Green LED	Language: C Architecture - **User Inputs** ○ Keypad ○ Dial - **External Inputs** ○ Open circuit detection Low voltage ○ Open circuit detection High voltage ○ Battery Voltage ○ Cable ID x 3 ○ Accelerometer - **Outputs** ○ Display Menu ○ Display Main Screen ○ Green LED	NO **(d), (g)**	

Device Name:	STIMPOD ST2-3010	STIMPOD NMS450	Affects Indications for Use / Technology	Comments
	(Closed Circuit) ○ Red LED (Open Circuit) ○ Buzzer Alarm ○ Square Wave Stimulation Low Voltage ○ No Square Wave Stimulation High voltage	(Closed Circuit) ○ Red LED (Open Circuit) ○ Buzzer Alarm ○ Square Wave Stimulation Low voltage ○ Square Wave Stimulation High voltage		
Waveform	Monophasic Square Wave	Monophasic Square Wave	NO **(h)**	
Pulse Width (3)	0.1, 0.2, 0.3ms	0.05, 0.1, 0.3, 0.5, 1ms	NO **(h)**	Similar and within the range of the predicate
Shelf Life (7)	5 Years	5 Years	NO **(e)**	
Control Mechanism (3)	Digitally controlled by a microprocessor	Digitally controlled by a microprocessor	NO **(g)**	
Electronics	PCB:2 layer board POWER SOURCE:: 4 x AAA POWER SUPPLY: Switch Mode MAX POWER CONSUMPTION: ± 40mA MAX VOLTAGE: 100V	PCB:2 layer board POWER SOURCE:: 4 x AAA POWER SUPPLY: Switch Mode MAX POWER CONSUMPTION: 79mA MAX VOLTAGE: 400V	NO **(h)**	
Device Cleaning	**Cleaning:** Soap and water, applied with a damp cloth is suitable to clean and disinfect the STIMPOD. It is imperative that no moisture penetrates the STIMPOD. **Disinfecting**: Any commercially available methanol - free disinfectant in an ethyl alcohol base can be used for disinfection	**Cleaning:** Soap and water, applied with a damp cloth is suitable to clean and disinfect the STIMPOD. It is imperative that no moisture penetrates the STIMPOD. **Disinfecting**: Any commercially available methanol - free disinfectant in an ethyl alcohol base can be used for disinfection.	NO **(e)**	
510(k)	This submission.	K102084		

A detailed comparison has provided the following conclusions:
The bolded letters reference the relevant section on the table above. This is indicated in the column “affects indications for use / Technology”

Clinical Use

The target populations on which product usage would occur are the same as those of the cited predicate device.
The Stimpod ST2-3010 employs a subset of the indications for use of the Stimpod NMS450, the same contraindications for use, and the same warnings and precautions within labelling

Each of the above devices:

- used for the same clinical condition or purpose; **(a)**
- have similar relevant critical performance according to expected clinical effect for specific intended use. **(b)**

Technical Characteristics

The STIMPOD ST2-3010 is equivalent to the identified predicate in design and utilized materials of construction of the currently marketed aforementioned predicate devices.

Also, the principles of operation of the subject device are directly equivalent to those of the cited predicate

Each of the above devices:

- are used under similar conditions of use; **(c)**
- have similar specifications and properties; **(d)**
- are of similar design; **(e)**
- use similar deployment methods; **(f)**
- have similar principles of operation; **(g)** and
- have similar electrical performance. **(h)**

As indicated in the table above, the ST2-3010 and the NMS450 are exact matches on technical characteristics, with the following exceptions:

1. Current Range 0-10 compared to Current Range 0-5 (Nerve Locating)
    a. The ST2-3010 can adjust the current up to 10mA. The NMS450 however can only adjust the current to 5mA. However, the NMS450 can adjust pulse width up to 1ms, whereas the ST2-3010 can only adjust pulse width up to 0.3ms. That concludes that the maximum charge output of the ST2-3010 is 3uC, which is only 60% of the maximum charge output (5uC) of the NMS450. Thus patient safety is not affected by this change.
2. Pulse width options 0.1, 0.2, 0.3ms compared to 0.05, 0.1, 0.3, 0.5, 1.0ms
    a. The pulse width options of the ST2-3010 are a subset of the pulse width options of the NMS450, and therefor do not affect patient safety.
3. No High Voltage stimulation vs. High Voltage Stimulation
    a. As the ST2-3010 is only a nerve location device, it only employs the low voltage section of the electrical circuit, exactly the same as the Nerve Locating mode on the NMS450

Biological Characteristics

Each of the above devices has:

- no known biocompatibility issues; **(i)** and
- no known effect on the environment, or to other devices.

Contents ST2-3010 Peripheral Nerve Stimulator Kit.

The Kit will include the following parts:

a. Peripheral Nerve Stimulator
b. Stimulation Adaptor Cable
c. Carrying Case
d. Instructions for Use

Note: Needles, ECG electrodes and batteries are not supplied